In its request, Calgene claimed that the FLAVR SAVR™ tomato is a food that is subject to a categorical exclusion from the National Environmental Policy Act (21 CFR 25.24(b)(7)). Calgene noted that an environmental assessment was filed in its submission on the use of the kanamycin resistance gene (Docket No. 90A–0416). The firm also noted that: (1) Environmental assessments with findings of no significant impact have been prepared in conjunction with field trials of the FLAVR SAVR™ tomato conducted under U.S. Department of Agriculture (USDA) regulations, and (2) environmental issues associated with the commercial growing of FLAVR SAVR™ tomatoes will be addressed as part of the firm's submission to USDA for exemption from the permit requirement under the Plant Pest Act (7 CFR part 340).

FDA believes that the decision as to whether Calgene must file an environmental assessment may depend upon the regulatory status of the FLAVR SAVR™ tomato. Therefore, FDA is deferring a statement of its position on whether Calgene must file an environmental assessment for the FLAVR SAVR™ tomato until the agency responds to Calgene's request, at which time FDA will also address whether an environmental assessment is required.

FDA encourages interested parties to submit comments on Calgene's request regarding both human and animal food safety and environmental safety, particularly with respect to the following:

1. Any relevant scientific issues that have not been addressed in the submission, including comments on environmental safety issues that were not addressed previously in the advisory opinion request on the use of the kanamycin resistance gene; and

2. Any available substantive information that bears on the relevant scientific issues.

FDA has received comments from interested parties in response to the Federal Register notice of May 1, 1991, concerning the use of the kanamycin resistance gene, including its use in the agency's review of the current request. Therefore, these comments need not be resubmitted in response to this notice.

FDA has filed Calgene's request at the Dockets Management Branch (address above). The filing by the agency of an advisory opinion request is a procedural matter and does not obligate the agency to issue such an opinion, nor does such filing reflect an agency decision on the substantive merits of the request.

The agency is not required to publish a notice of filing of a request for a formal advisory opinion, and, therefore, does not routinely publish such notices. However, FDA believes that publication of this notice is in the public interest because the agency requests comments from interested members of the public, industry, and other governmental agencies, and because this is the first such request made to FDA regarding the status of a whole food produced by the new methods of gene transfer.

Interested persons may, on or before July 28, 1992, review the request or file comments (four copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). A copy of the request and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 92–12659 Filed 5–28–92; 3:57 pm]

BILLING CODE 4160–01–M

[Docket No. 92E–0115]

Determination of Regulatory Review Period for Purposes of Patent Extension; Acel-Imune®; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of May 1, 1992 (57 FR 18887), that announced its determination of the regulatory review period for purposes of patent extension for Acel-Imune® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed). The document was published with some inadvertent mathematical errors. The document stated, "Of this time, 400 days occurred during the testing phase of the regulatory review period, while 1,602 days occurred during the approval phase." It should have stated, "Of this time, 434 days occurred during the testing phase of the regulatory review period, while 1,568 days occurred during the approval phase." This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

In FR Doc. 92–10141, appearing on page 18887 in the Federal Register of Friday, May 1, 1992, the following corrections are made: On page 18888, in the first column, in the second complete paragraph, in line 4, "400" is corrected to read "434"; and in line 6, "1,602" is corrected to read "1,568".

Dated: May 21, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92–12547 Filed 5–28–92; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–739–FN]

RIN 0938–AF55

Medicare Program; Recognition of the Community Health Accreditation Program Standards for Home Care Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This final notice recognizes accreditation by the Community Health Accreditation Program (CHAP), a subsidiary of the National League for Nursing (NLN), for home health agencies (HHAs) that wish to participate in the Medicare Program. As a result of this recognition, HHAs accredited by CHAP are deemed to meet the Medicare conditions of participation for HHAs to the extent described in this notice. This final notice sets forth certain specific requirements with which CHAP must comply to maintain Medicare recognition of its HHA accreditation program.

EFFECTIVE DATE: The provisions of this notice are effective August 27, 1992.

FOR FURTHER INFORMATION CONTACT: John J. Thomas, (410) 966–4623

SUPPLEMENTARY INFORMATION

I. Background

Providers of health care services participate in the Medicare program in accordance with a provider agreement. Generally, in order to enter into a provider agreement, an entity must first be certified by a State survey agency as complying with the requirements set forth in Federal law and regulations. Providers are subject to regular surveys by State survey agencies to ensure that the providers continue to meet these requirements.

The Social Security Act (the Act) includes provisions that permit exemption of certain provides of services form routine surveys by State survey agencies for determining compliance with Medicare conditions of participation. Specifically, section 1865(a) of their Act permits the "deeming" of providers as meeting the